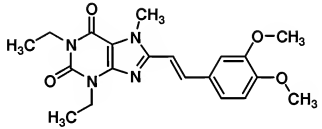
b.) Remarks

The claim have been amended in order to recite the present invention with the specificity required by statute. No new matter has been added.

As the Examiner is well-are, the claimed invention is a method for suppressing formation of impurities due to dimerization of a (E)-8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione represented by formula (IB)



(IB)

or a pharmaceutically acceptable salt thereof, in a solid formulation, which comprises providing iron oxide in the solid formulation, wherein formation of impurities due to dimerization of the compound or the pharmaceutically acceptable salt is suppressed.

Shimada does not refer to any stability issue of a xanthine compound, let alone suppressing formation of impurities due to dimerization of 8-styrylxanthines in a solid formulation.

Sako discloses combining iron oxide and polyethylene oxide. Sako discloses a method for improving stability of polyethylene oxide in a formulation, whereby changes in drug release from a preparation containing such polyethylene oxide can be prevented. However, Sako does not relate at all to (E)-8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione. Nor does Sako disclose formation of

impurities of any drug, much less teach or suggest suppressing formation of impurities of any drug. Sako plainly does not disclose or relate to presenting dimerization of any compound.

Harrison simply discloses a controlled release preparation comprising a xanthine derivative and polyethylene oxide, but Harrison does not relate to (E)-8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione, Harrison does not refer to formation of impurities of any drug, and Harrison dose not disclose dimerization of any compound.

There is no reason from the prior art why one of ordinary skill in the art would combine (E)-8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methyl-3,7-dihydro-1H-purine-2,6-dione and iron oxide for suppressing formation of impurities due to dimerization of such compound, nor is doing so "obvious to try" under KSR.

This deficiency is not at all addressed by Suzuki, which too teaches neither that there is any stability issue of the xanthine compounds in a coated solid formulation, nor that such xanthine compounds undergo dimerization.

Claims 1 and 8-12 remain presented for continued prosecution.

Entry hereof is earnestly solicited.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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